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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,650	02/12/2001	Robert John D'Amato	43170-253692 (05213-0493)	2466
23370	7590	01/12/2006	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/780,650	Applicant(s) D'AMATO ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-32, 34, 36-40 and 43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-32, 34, 36-40 and 43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/05</u> . | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The provisional rejection of claim 34 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/077,142 (now US patent 6,908,910) is withdrawn.
3. The provisional rejection of claims 26-32, 34 and 36-40 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/617,150 (now US patent 6,930,128) is withdrawn.
4. The provisional rejection of claims 27, 28 and 30 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/918,627 (allowed September 21, 2005) is maintained.
5. The provisional rejection of claims 26-32, 34 and 36-40 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/379,991 is maintained and claim 43 is provisionally rejected

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under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/370,991.

It is noted that the cited copending Application is not abandoned as indicated by applicant in the response dated October 31, 2005.

6. The provisional rejection of claims 26, 27, 29-32, 34, 36-40 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/280,631 is withdrawn.

7. The provisional rejection of claims 26-32, 34 and 36-40 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/789,471 is maintained and claim 43 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 10/789,471.

Claim Rejections - 35 USC § 103

8. The rejection of claims 27 and 28 under 35 USC 103(a) over Seegers et al. is maintained.

Applicant's argues that in the field of cancer treatments, one cannot extrapolate the results obtained from in vitro studies to treatment in humans. Thus, according to applicant, the only reasonable expectation a person skilled in the art would have based on the cited reference is that 2-methoxyestradiol is a cytotoxic poison for MCF-7 and

HeLa cells in vitro. Applicant's argument was considered but not persuasive for the following reasons.

Although, in vivo testing, including clinical trials, is necessary for the development of any drug for human use, in vitro testing is routinely utilized to correlate to a particular therapeutic or pharmacological utility.

In the cancer art, MCF-7 and HeLa cells are routinely utilized in the testing of anticancer agents and the results obtained therein are routinely extrapolated to in vivo treatment methods. Attached are a number of articles in support of the examiner's position (see for example, Schumacher et al., 2001; Pribluda et al., 2000; US Patent No. 5,750,576). Schumacher et al., 2001 and Pribluda et al., 2000 give an overview of studies of 2-methoxyestradiol in various cell lines and its antiproliferative effect. US 5,750,576 discloses the effect of tamoxifen, a well-known anticancer agent, in MCF-7 cells (see especially col. 8, Table 3). If applicant needs additional articles showing the utilization of cancer cell lines in the testing of anticancer agents, the examiner is willing to provide said.

Applicant's attention is also directed to MPEP § 2107.03 (III) wherein it is stated that data from in vitro or animal testing is generally sufficient to support therapeutic utility. Therefore, based on the routine utilization of cancer cell lines in the testing of anticancer agents and the ability to reasonably predict the utility of these compounds in humans, it is the examiner's position that the utilization of 2-methoxyestradiol in the treatment of solid tumors, such as breast cancer is prima facie obvious based on the cited prior art.

Lastly, the examiner notes that the present specification lacks in vivo testing especially human studies. Thus, like the prior art, applicant is extrapolating data obtained from in vitro testing to treatment methods in humans. Therefore, based on applicant's argument and the lack of in vivo data in the present specification, is applicant suggesting that the present invention is based on an "obvious to try" to use 2-methoxyestradiol in the treatment of the various claimed disorders?

For these reasons and those given in previous Office Actions, the rejection of claims 27 and 28 under 35 USC 103(a) over Seegers et al. is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB

January 9, 2006